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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/537,266

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Yasuo Tano

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EXAMINER

LAVERT, NICOLE F

ART UNIT

PAPER NUMBER

3762

NOTIFICATION DATE

DELIVERY MODE

07/23/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/537,266	Applicant(s) TANO ET AL.	
	Examiner NICOLE F. LAVERT	Art Unit 3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 June 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 7 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 August 2008 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>6/1/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claim 7 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. There is no support within the specification for the claim limitation "...a foldable tube for bundling the plurality of signal wires together," in combination with the other elements in the claim since there is no support within the specification that the tube is foldable and/or made of a material that will allow said tube to be folded. The specification only provides support for the tube bundling said wires together.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various

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claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

3. **Claim 7** is rejected under 35 U.S.C. 103(a) as being unpatentable over Yagi (US 2004/0102843) in view of Byers et al. (US 4,969,468) and Krulevitch et al. (US 2003/0097166).

Yagi discloses an artificial vision system (e.g., Fig 1, 1) comprising: an external device to be disposed outside a body of a patient (e.g., Fig 1, 2); an image pickup device (e.g., Fig 1, 4); and an image processing device (e.g., Fig 1, 9) which generates a stimulation signal by processing an image captured by said image pickup device; an internal, implanted device (e.g., Fig 1, 3) including: a receiving device which receives a stimulation pulse signal and converts it into an electrical stimulation pulse signal (see Figure 1, 'reception'); and a plurality of electrodes (e.g., Fig 1, 11) which outputs the electrical stimulation pulse signal that is generated based on the image captured by the image pick up device thereby enabling the patient to visually recognize the image captured by said image pick up device (e.g., [0028]-[0030], [0053]-[0054] & [0059]).

Yagi discloses the claimed invention having an artificial vision system including a plurality of electrodes except wherein said system includes electrodes with a needle-shaped end that are adapted to be implanted in the eye so as to stick in a bundle of nerve fibers of an optic papilla of the eye and a plurality of signal wires which individually connect each said electrode and the receiving device covered with an insulating material with high biocompatibility and a

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foldable tube for bundling the plurality of signal wires together. Byers et al. teaches that it is known to use electrode arrays for electrically stimulating nerve fibers in which said arrays comprises needle-like contacts that are disposed along the optic nerve or the paths where the optic nerve enters the cortex, in which Byers et al. is also capable of meeting the functional use recitations presented in the claim of being "...implanted in the eyes so as to stick in a bundle of nerves fibers of an optic papilla..." since the disclosed needle electrodes can be placed and will stick in claimed locations [e.g., (col 7, ln 33-53) & (col 15, ln 4-13)]. Note that the optic papilla is the portion of the optic nerve formed by retinal ganglion cells axons as they enter said optic nerve, in which the optic papilla is the location of the eye along the pathways of the optic nerve. Krulevitch et al. teaches that it is known to use an electrode array that can be used for artificial vision in which said system comprises a plurality of conductive lines and/or leads (e.g., elements 16 & 23) patterned into the substrate of the electrode array (e.g., elements 21) and are further connected to the electrodes of the substrate (e.g., elements 22), wherein said conductive lines and/or leads are bundled together via a flexible, ribbon cable (e.g., element 24) that is used to connect said electrodes to the electronics of the artificial vision device, such as a component used for transferring an image signal to tissue in a retina {e.g., [0085] & (Figs 6 & 10)}. Note that the Examiner is interpreting the disclosed conductive lines and/or leads (e.g., elements 16 & 23) as being the plurality of signal wires which individually connect each electrode to the receiving device, in which the Examiner further notes that it is well known to those of skill that said conductive lines and/or leads are insulated via an insulative material, as is instantly claimed in order to selectively deliver and/or receive electrical energy via the electrodes and to safely provide electrical coupling between circuitry and said electrodes via a means that avoids

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exposing bodily tissue to stray and/or harmful energy. Also note that the Examiner is interpreting the disclosed ribbon cable (e.g., element 24) as being the claimed foldable tube used for bundling the plurality of signal wires together into one (e.g., see Fig 10) since the disclosed cable provides a flexible means of “bundling” the conductive leads together into a singular form so as to electrically couple the disclosed electrodes to the electronics of the device, in which it is known in the art that a cable comprises a centrally disposed opening and/or lumen means in which said leads are disposed and bundled within. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system as taught by Yagi with the needle electrode array adapted to be disposed on the optic nerve comprising conductors extending from said needle electrodes to other electrical circuitry as taught by Byers et al. and the plurality of wires bundled together via a ribbon connector means as taught by Krulevitch et al., since such a modification would provide the artificial vision system including a plurality of electrodes with a needle-shaped end that are adapted to be implanted in the eye so as to stick in a bundle of nerve fibers of an optic papilla of the eye and a plurality of signal wires which individually connect each said electrode and the receiving device covered with an insulating material with high biocompatibility being bundled together via a foldable tube for providing the predictable results pertaining to providing a needle-shaped electrode used to penetrate into the optic nerve of a patient for effectively making electrical contact within the nerve fibers of said optic nerve so as to enhance optical functions of a patient (e.g., Byers, col 15, ln 4-13) and providing the results pertaining to providing an electrode cable comprising a plurality of wires suitable for use as an electrical connection between an electrical stimulating device and connectable to the proximal end of the cable an electrode(s) connected to the distal

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end of the cable, wherein said plurality of wires are shielded from stray electrical energy that may be harmful to a patient by way of an insulative, tubular sheath {e.g., Krulevitch, [0085] & (Fig 10)}.

Response to Arguments

4. Applicant's arguments with respect to claim 7 is have been considered but are moot in view of the new ground(s) of rejection.

5. Applicant's arguments filed 22 June 2010 have been fully considered but they are not persuasive. The Applicant argues that the secondary reference, Byers, was not intended to be used in the eyeball of a patient in which provides no reasonable rationale to combine. The Examiner disagrees and further points out that the present claim cites functional use language such as "...a plurality of electrodes...adapted to be implanted in the eye so as to stick in a bundle of nerve fibers of an optic papilla...for placing its end in an optic nerve of the eye..." and as long as the prior art is CAPABLE of meeting the claimed limitation the prior art reads over the claim, therefore the disclosed electrode array comprising needle-like contact that electrically stimulate nerve fibers disposed along the optic nerve or the paths where the optic nerve enters the cortex is capable of meeting the functional use recitations presented in the claim of being "...implanted in the eyes so as to stick in a bundle of nerves fibers of an optic papilla..." since the disclosed needle electrodes can be placed and will stick in claimed locations [e.g., (col 7, ln 33-53) & (col 15, ln 4-13)]. In addition, the Examiner again notes that the optic papilla is the portion of the optic nerve formed by retinal ganglion cells axons as they enter said optic nerve, in which the optic papilla is the location of the eye along the pathways of the optic nerve therefore there is strong rational to combine Byers et al. with the primary reference.

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6. Applicant's arguments, filed 22 June 2010, with respect to the 112, first paragraph claim rejections have been fully considered and are persuasive and have been withdrawn.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NICOLE F. LAVERT whose telephone number is (571)270-5040. The examiner can normally be reached on M-F 7:30-5:00p.m. (alt. Fridays).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carl Layno can be reached on 571-272-4949. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/George R Evanisko/
Primary Examiner, Art Unit 3762

/Nicole F. LaVert/
Examiner, Art Unit 3762